IgG Multi-Purpose (MPR) Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL607GG	1 x 50 ml 1 x 10 ml	IgG - 1 IgG - 2	2 - 8°C
GL617GG	5 x 50 ml 5 x 10 ml	IgG - 1 IgG - 2	2 - 8°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Immunoglobulin (IgG) in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

IgG is the major Immunoglobulin produced by the plasma cells. It accounts for 70 to 75% of the total Immunoglobulins. Its' major function is neutralisation of toxins and destruction or removal of infectious agents. IgG antibodies are produced in response to most bacteria and viruses. IgG has 4 main sub classes (IgG 1, IgG2, IgG3 and IgG4). Polyclonal IgG increases may be present in systemic lupus erythematosis, chronic liver disease, infectious disease and cystic fibrosis. Monoclonal IgG increases are present in IgG myeloma. Decreased levels of IgG are found in congenital and acquired immunodeficiency diseases of selective IgG sub class deficiencies. Decreased IgG concentrations are also seen in protein losing enteropathies, nephorotic syndrome and through the skin from burns.

PRINCIPLE OF THE TEST:

This assay is based on the reaction between IgG antigen and anti-IgG antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of IgG in the sample.

IgG antigen + Anti-IgG antibody ⟶ Antigen/antibody complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear colourless liquid.
Reagent 2: Pale beige liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Product is not hazardous under EU specification. Contain minute quantity of Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	TRIS Buffer pH 7.6 with PEG	18.16 mmol/l
	Sodium Chloride	123.20 mmol/l
	DETERGENT & PRESERVATIVE	---
Reagent 2	TRIS Buffer pH 7.6	18.16 mmol/l
	Anti IgG antibody	---
	PRESERVATIVES	---

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label. Prepare a range of 6 standards by serially diluting Calibrator (GL9605) in saline as follows:

Dilution	Neat	1/2	1/4	1/8	1/16	1/32
Factor	1	0.5	0.25	0.125	0.063	0.032

TYPE OF SPECIMEN:

Use serum or heparin/EDTA plasma as specimen.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Plasma/serum should be separated from cells within 2 hours after collection.

Stability: up to 3 months at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
Specific Protein Calibrator	GL9605	Photometer	N/A
Specific Protein Control Level 1	GL9006	General Laboratory Equipment	N/A
Specific Protein Control Level 2	GL9016	Saline solution 0.9 g/l NaCl	N/A

Assay procedure:
Wavelength: λ: 700 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	**Calibrator**	**Sample**
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	5 µl
Calibrator	----	5 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 5 minutes, against the blank			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after 10 minutes, against the blank			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory Q.C. Programme.

CALCULATION:

- Calculate the Δ Abs for each standard and construct a calibration curve. Δ Abs = OD2 – OD1.
- Calculate Δ Abs for the samples. Determine the corresponding concentration from the calibration curve
- Calculate sample/controls net OD. Determine the corresponding concentration from the calibration curve.

(Conversion Factor: mg/dl x 0.01 = g/l)

EXPECTED VALUES: [4]

7 to 16g/l * (700 to 1600mg/dl)

*Reference values according to CRM 470 Protein Standardisation.

Each laboratory should establish its own reference range. IgG results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear across the calibration range.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Prozone:
The system did not show prozone phenomena at least up to 55 g/l. (5500 mg/dl).

Interfering substances:
Results of study are as follows:

Bilirubin (mixed isomers):	Less than 10% interference up to 600 µmol/l Bilirubin.
Haemolysis:	Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia:	Less than 10% interference up to 5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.09g/l (9 mg/dl).

Precision:

Within Run N = 20	Mean *(g/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(g/l)*	*SD*	*% CV*
Level 1	6.7	0.15	2.26	Level 1	6.6	0.13	1.92
Level 2	10.5	0.31	2.95	Level 2	10.2	0.22	2.20

Method Comparison:
Using 50 samples, a comparison, between this IgG test (y) and another commercially available test (x), gave the following results:

y = 0.930x + 1.285	r = 0.909	Sample range: 2.7 to 20.8 g/l

BIBLIOGRAPHY:

1. Gitlin D, Edelhoch HJ. Immunol. 1951, 66, 76-78.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54 and 462-494.
3. Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes; Pre-analytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT Verlag, 1996.
4. Consensus values of the Deutsche Gesellschaft fur Laboratoriums-medizin, the Deutsche Gesellschaft fur Klinische Chemie and the Verband der Diagnostica-Industrie.V. (VDGH). DG Klinische Chemie Mitteilungen 1995; 41:743-748.

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
BUF	Buffer	Ab	Antibody
CAL	Calibrator	CE	CE Mark - Device comply with the Directives 98/79/EC
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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